641—154.69(124E) Requirements of the department.

154.69(1) *Laboratory testing requirements and acceptance criteria.* The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The department shall provide manufacturers and laboratories no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. The document shall:

a. Describe the minimum number of sample units and reserve samples required for testing by the laboratory;

b. Describe an option for manufacturers to reduce the amount of testing conducted by allowing compositing of sample units or other techniques that reduce the number of tests required without compromising the safety of the products once a manufacturer has satisfactorily completed a control study for a specific extraction or production process;

c. Describe the minimum requirements for sample size and testing intervals for stability testing;

d. Be available on the department's website (www.idph.iowa.gov).

154.69(2) *Review and approval of manufacturer sampling protocols.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's sampling protocols required pursuant to subrules 154.26(2) and 154.26(3).

154.69(3) *Review and approval of manufacturer stability-testing procedures.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures required pursuant to subrule 154.26(4).

154.69(4) *Establish a laboratory review committee.* The department shall establish a laboratory review committee to assist with the review of applications by laboratories and the establishment of accepted laboratory testing standards and practices.

154.69(5) *Review of laboratory applications.* The department shall establish a process to review applications from prospective medical cannabidiol testing laboratories. Prospective laboratories shall submit an application to the department on a form created by the department. The department shall determine whether the laboratory meets the criteria for an independent medical cannabidiol testing facility as set forth in the definition of "laboratory" in Iowa Code section 124E.2 in addition to determining whether the laboratory meets laboratory requirements pursuant to rules 641—154.70(124E) to 641—154.76(124E).

154.69(6) *Regulation of independent laboratories.* The department shall determine on an annual basis whether any approved independent laboratory continues to meet criteria as set forth in the definition of "laboratory" in Iowa Code section 124E.2 and laboratory requirements pursuant to rules 641—154.70(124E) to 641—154.76(124E). The department shall establish a process for the annual review of approved independent laboratories. An independent laboratory is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

[**ARC 4078C**, IAB 10/10/18, effective 11/14/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]